No. 2015-1499

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMGEN INC. and AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

v.

SANDOZ INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California, Case No. 3:14-cv-04741-RS, Judge Richard Seeborg

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SANDOZ INC.'S OPPOSITION TO EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL

NON-CONFIDENTIAL VERSION

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CERTIFICATE OF INTEREST

Counsel for defendant-appellee Sandoz Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Sandoz Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party or amicus curiae represented by me are:

Sandoz Inc. is an indirect, wholly owned subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or are expected to appear in this court are:

Morrison & Foerster LLP: Rachel Krevans, Deanne E. Maynard, Grant J. Esposito, Joseph R. Palmore, Erik J. Olson, David C. Doyle, Marc A. Hearron, Anders T. Aannestad, Eric C. Pai, Stephen D. Keane, Julie Y. Park. Kirkland & Ellis LLP: James F. Hurst, Michael D. Shumsky, John K. Crisham, Reid P. Huefner.

Dated: April 24, 2015 /s/ Deanne E. Maynard

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CONFIDENTIAL MATERIAL

Materials that were made confidential pursuant to the protective order have been redacted from the non-confidential version of the brief. These materials include confidential business information from documents and exhibits filed in the district court.

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INTRODUCTION

This is not a typical motion by a patentee seeking an injunction pending appeal. Amgen's appeal involves *no* claim of patent infringement. Instead, Amgen seeks to enjoin launch of Sandoz's FDA-approved biosimilar filgrastim product based solely on Sandoz's purported violations of procedures of the Biologics Price Competition and Innovation Act ("BPCIA"), Pub. L. No. 111-148, 124 Stat. 804 (2010). But the BPCIA contains no mechanism for Amgen to preclude Sandoz from launching absent a showing of patent infringement. Amgen has not attempted to make any such showing, nor sought a preliminary injunction based on any patent claim. To the contrary, Amgen repeatedly has stated that its material U.S. patents for filgrastim expired in 2013.

Amgen nonetheless argues that Sandoz's purported violations of the BPCIA entitle Amgen to an injunction under *state law*. The district court correctly rejected Amgen's state-law claims because Sandoz did not act "unlawfully" under the BPCIA. The court also properly rejected Amgen's request for an injunction pending appeal, finding as fact that Amgen's "tenuous and highly contingent showing of irreparable harm forecloses injunctive relief." A2080. Nothing in Amgen's motion undermines that finding. Indeed, Amgen cannot establish ***any*** of the four factors required to warrant an injunction pending appeal.

First, Amgen has not shown a strong likelihood of success on appeal.

The BPCIA created an abbreviated pathway for the FDA to license "biosimilar" products – i.e., biological products that are "highly similar" to already approved biological products. *See* 42 U.S.C. § 262(i)(2). The statute includes a carefully reticulated regime for the resolution of any patent disputes between biosimilar applicants and sponsors of approved biological products. In particular, the BPCIA creates a new artificial-infringement action, allowing sponsors to assert their patent rights before any actual infringement. 35 U.S.C. § 271(e)(2)(C). The particular contours of any pre-approval suit depend on the actions taken or not taken at each step of a multi-step process of information exchange between the applicant and the sponsor regarding the sponsor's possible patent claims. 28 U.S.C. § 2201(b); 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*). At each step, Congress carefully spelled out both the action the party "shall" take to continue with the process and, if the party declines, what follows.

At issue here, Section 262(*l*)(2)(A) provides that within 20 days of FDA acceptance of a biosimilar application, the applicant "shall provide" a copy to the sponsor. 42 U.S.C. § 262(*l*)(2)(A). The district court correctly concluded that the "shall" in this provision establishes a mandatory condition precedent to taking advantage of the patent-exchange process. The BPCIA expressly contemplates that an applicant might not provide its application and lays out how patent disputes are resolved in that event: patent-infringement litigation, with the scope and

timing at the sponsor's sole discretion. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). Taking a path that the BPCIA expressly provided is not unlawful.

Also at issue is Section 262(*l*)(8)(A), which provides for "[n]otice of commercial marketing" 180 days before marketing. Amgen argues Sandoz "violated" that provision by giving notice *too early*, contending notice cannot be given until after FDA licensure. The district court correctly rejected Amgen's reading, which effectively would transform the "[n]otice" provision into an automatic 180-day bar against marketing – essentially an automatic, bondless injunction – even where the sponsor has no patents.

Even if Amgen's interpretation of the BPCIA were correct, it still could not obtain an injunction against commercial marketing. Congress expressly provided that the BPCIA patent remedies are the "*only remedies* which may be granted by a court" for an applicant's submission of a biosimilar application without providing a copy to the sponsor, 35 U.S.C. § 271(e)(4) (emphasis added), and the statute likewise provides a specific remedy (immediate patent litigation) for the failure to provide a notice of commercial marketing, 42 U.S.C. § 262(*l*)(9)(B).

Second, as the district court found as fact, Amgen's claimed harms are "tenuous and highly contingent." A2080. As Amgen acknowledges, the district court concluded that "any detriment Amgen endures due to market entry of Sandoz's biosimilar product is only undue if Sandoz has infringed an Amgen

patent," which Amgen has not tried to show. *Id.* That conclusion is correct, as the BPCIA requires proof of infringement to keep a biosimilar off the market.

The district court also made a second, independent finding on irreparable harm, which Amgen ignores. The court found that "Amgen's showing of potential price erosion, harm to Amgen's customer relations and goodwill, and diversion of Amgen's sales representatives' energy, is speculative." *Id.* Amgen cannot show that that finding is clearly erroneous.

Finally, the balance of equities and public interest favor Sandoz. Sandoz invested years of effort and tens of millions of dollars to have the first biosimilar filgrastim in the United States. Competitors' products are expected this year. Even a brief injunction would jeopardize the first-to-market advantage Sandoz earned. The public interest also would be substantially harmed by denying patients access to Sandoz's filgrastim and the price competition promised by the BPCIA.

BACKGROUND

For 24 years, Amgen has marketed the biological product filgrastim under the brand name Neupogen®. A5. Since February 2014, Amgen has publicly stated: "Our material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013. We now face competition in the United States . . . ." A915; A960.

On July 7, 2014, the FDA accepted for review Sandoz's application for biosimilar filgrastim. A5. The next day, Sandoz notified Amgen of its application,

advised Amgen that FDA approval was expected in the first half of 2015, and informed Amgen that Sandoz intended to launch its product immediately upon FDA approval. A1472-73. Sandoz also offered to provide its application on a confidential basis. *Id.* Amgen declined Sandoz's offer. A1481-82.

Concerned about sharing its application with a competitor, and in light of Amgen's statements that it has no material, unexpired patents for filgrastim, Sandoz determined that subjecting itself to an immediate patent suit was the most expeditious path to resolution of any patent claims. A1495-97. On July 25, 2014, Sandoz informed Amgen that "Amgen [was] entitled to start a declaratory judgment action under 42 U.S.C. § 262(*l*)(9)(C)," A1496, and that Amgen could "obtain access to the biosimilar application" in that suit under court-ordered confidentiality protections. A1495. Sandoz again offered to provide Amgen its application under industry-standard confidentiality protections. A1495-1503. Amgen rejected that offer. A1505-07.

Months later, on October 24, 2014, Amgen brought a claim under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, alleging that Sandoz's purported "violations of the BPCIA satisfy the 'unlawful' prong of § 17200." A74. Amgen also brought a state-law claim for conversion, alleging that Sandoz wrongfully used Amgen's license. Additionally, Amgen brought a claim for artificial infringement of U.S. Patent No. 6,162,427

("'427 patent"). Sandoz answered and counterclaimed. A271-88.

The parties cross-moved for partial judgment on the pleadings. And, more than three months after filing suit, Amgen moved for a preliminary injunction – based only on its state-law claims, not on alleged patent infringement. On February 9, 2015, after the court issued Sandoz's proposed protective order, Amgen finally accepted Sandoz's application. A734; A1353.

On March 19, 2015, the district court denied Amgen's motions and granted Sandoz's motion. A1-19. The court held that it was lawful for Sandoz to withhold its application, as the BPCIA contemplates applicants might, and that the sole consequence is a sponsor may start immediate patent litigation, as Amgen already has done. A9-12. The court also held that, under the plain text of Section 262(*l*)(8)(A), it was "not wrongful for Sandoz to give Amgen its 180 days' notice" of commercial marketing before FDA approval. A14. Additionally, the court noted that "[t]he effect of Amgen's position—that Congress intended for sponsors to resort to state laws to enforce mandatory provisions in a federal statute and collect remedies for their violation, in addition to exacting the consequences written expressly into the legislation itself—is unworkable." A15. Finally, the court denied Amgen's preliminary injunction motion because, among other reasons, Amgen's asserted irreparable harms are "at best highly speculative." A18.

The district court later entered final judgment on the non-patent claims and

counterclaims and granted the parties' joint request to stay all other proceedings, including Amgen's patent-infringement claim. A20-23. Although the FDA had approved Sandoz's biosimilar filgrastim product on March 6, 2015 (A1774-82), Sandoz agreed not to launch until the earlier of this Court's ruling on Amgen's motion for an injunction pending appeal, or May 11, 2015. A1946.

On April 15, 2015, the district court denied Amgen's motion for an injunction pending appeal. A2078-80. The court held Amgen unlikely to prevail on appeal. It also found Amgen's claimed harms "tenuous and highly contingent" because: (1) Amgen's claimed harms are "speculative," and (2) in any event, Amgen's claimed harms are "only undue if Sandoz has infringed an Amgen patent," which Amgen has not tried to show. A2080.

ARGUMENT

I. AMGEN'S MOTION SHOULD BE DENIED

An injunction is an "extraordinary remedy" requiring "a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). An injunction pending appeal requires a court to consider

> (1) whether the . . . applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent [an injunction]; (3) whether issuance of the [injunction] will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Hilton v. Braunskill, 481 U.S. 770, 776 (1987). Satisfying one factor does not

lessen the requirement to establish the others. *See Winter*, 555 U.S. at 21-22.[1]

Where, as here, the district court denied an injunction pending appeal under Federal Rule of Civil Procedure 62(c), a motion under Federal Rule of Appellate Procedure 8 should be denied unless the district court's decision was an abuse of discretion or its factual findings are clearly erroneous. *Regents of the Univ. of Cal. v. American Broad. Cos.*, 747 F.2d 511, 522 n.7 (9th Cir. 1984); *Lightfoot v. Walker*, 797 F.2d 505, 507 (7th Cir. 1986); Fed. R. Civ. P. 52(a)(6).

Amgen has not established *any* of the four factors required for the entry of an injunction pending appeal – much less *all* of them.

A. Amgen Cannot Make A Strong Showing Of A Likelihood Of Success On The Merits

1. The district court correctly held that it was lawful for Sandoz not to provide its application under Section 262(l)(2)(A)

The district court properly concluded that Sandoz did not act "unlawfully" when it took a path expressly laid out by the BPCIA: withholding its application and thus subjecting itself to the possibility of immediate patent litigation.

The BPCIA creates an integrated regime for resolving any patent disputes involving biosimilars, preferably before FDA approval. It amends the Patent Act

[1] Although Amgen argued in district court that it need show only "serious legal questions" if the balance of harms tips sharply in its favor (A1978), it waived that argument by not pressing it here. For good reason: that is not the standard. *See Nken v. Holder*, 556 U.S. 418, 434 (2009). In any event, the district court correctly held Amgen cannot meet even that standard. A2080 n.2; *see* A16-17.

to make submission of a biosimilar application to the FDA an artificial act of infringement under certain circumstances, thus permitting litigation before any actual infringement. 35 U.S.C. § 271(e)(2)(C). It also establishes a multi-step process in 42 U.S.C. § 262(*l*) that determines who can bring such a suit, when it can be brought, and for what relief. Although each subsection (*l*) step begins with "shall," the BPCIA contemplates that the applicant or the sponsor might not pursue the patent-exchange process to completion and expressly provides the consequences for not doing so. A2050-51 (showing consequence at each step).

As the district court explained, "to continue the process or to terminate it confers advantages and disadvantages" for both parties. A5. Amgen is thus wrong that withholding of an application brings only benefits for the applicant and harms for the sponsor. Mot. 11, 16. If the application is withheld, the sponsor gains the right to file an immediate, pre-launch suit based on the act of artificial infringement, 35 U.S.C. § 271(e)(2)(C)(ii), and the applicant loses its right to forestall it, 42 U.S.C. § 262(*l*)(9)(A), (C). The sponsor can then obtain the biosimilar application in discovery (as Amgen did here). The applicant also loses the control it would otherwise have over which patents, or how many, the sponsor can assert. *Compare* 42 U.S.C. § 262(*l*)(9)(C), *with id.* § 262(*l*)(3)-(5). The sponsor alone decides whether and when to sue and can delay suit until after FDA approval, effectively forcing the applicant to launch at risk.

In light of the BPCIA's multiple procedural paths to resolving any substantive patent rights, the district court correctly concluded that the "shall" in Section (*l*)(2)(A) denotes a condition precedent to engaging in the patent-exchange process, rather than a mandate that the process be initiated in all circumstances. A9-11; *see County of Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082 (D. Minn. 2013) (similarly interpreting "shall" as a condition precedent), *aff'd*, 776 F.3d 947 (8th Cir. 2014). That interpretation gives full and ordinary meaning to the word "shall." *If* an applicant wishes to engage in the patent-exchange process, then it *must* provide its application to the sponsor within 20 days of FDA's acceptance of the application. 42 U.S.C. § 262(*l*)(2)(A). But "[*i*]*f* a subsection (k) applicant fails to provide [its] application," then the sponsor can immediately commence patent litigation under the BPCIA's amendments to the Patent Act making that failure an act of artificial infringement. *Id.* § 262(*l*)(9)(C) (emphasis added); *see* 35 U.S.C. § 271(e)(2)(C)(ii). In that event, the statute shifts the parties onto a different track to resolve patent disputes: immediate, pre-launch patent litigation. As the district court correctly concluded (A9-12), it cannot "violate" the BPCIA to choose this track established by the BPCIA itself.

Contrary to the district court's holistic interpretation of the BPCIA, Amgen insists on reading the word "shall" in Section 262(*l*)(2)(A) in isolation. But each statutory provision must be read "in context and with a view to [its] place in the

overall statutory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Other provisions confirm that the word "shall" in subsection (*l*) does not denote a mandatory requirement in all circumstances.

Subsection (*l*)(6) provides that at the end of the patent-exchange process, "the reference product sponsor *shall* bring an action for patent infringement" on specified patents within 30 days. 42 U.S.C. § 262(*l*)(6) (emphasis added). Nothing in the BPCIA suggests that Congress mandated that one private party sue another, or else the sponsor commits an "unlawful" act. To the contrary, despite the word "shall," the BPCIA expressly envisions that suit might be brought "*after* the expiration of the 30-day period." 35 U.S.C. § 271(e)(6)(A)(ii)(I) (emphasis added). In that event, "the sole and exclusive remedy that may be granted by a court . . . shall be a reasonable royalty." *Id.* § 271(e)(6)(B).

Contrary to Amgen's contention (Mot. 10-11), the district court's interpretation is consistent with the use of "shall," "may," "required," and "fails" in subsection (*l*). Providing the application within 20 days is "required" for an applicant to participate in the patent-exchange process, and if the applicant "fails" to satisfy that condition precedent, statutory consequences follow. If an applicant provides its application, it also "*may* provide to the reference product sponsor additional information," but doing so is not required to participate in the process. 42 U.S.C. § 262(*l*)(2)(B) (emphasis added).

2. The district court correctly held that it is not unlawful to provide notice under Section 262(l)(8)(A) 180 days before commercial marketing, rather than after FDA licensure

Nor has Amgen established a strong likelihood of success on its contention that Sandoz acted "unlawfully" under Section 262(*l*)(8)(A) by providing its notice of commercial marketing too early. That provision states that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). As the district court correctly held (A12-14), Sandoz satisfied that provision by giving notice in July 2014, more than 180 days before commercial marketing.

The text of Section 262(*l*)(8)(A) forecloses Amgen's argument that notice may not be given before the product is "licensed under subsection (k)." Mot. 12-13 (quoting 42 U.S.C. § 262(*l*)(8)(A)). The "before" in Section 262(*l*)(8)(A) modifies "the date of the first commercial marketing," so the provision is satisfied so long as notice comes at least 180 days before that event. The use of "licensed" simply recognizes that a product cannot legally be "commercial[ly] market[ed]" until it is "licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A); *see id.* § 262(a)(1)(A). After all, it is a "subsection (k) *applicant*" – not the "holder" of an approved application – that is expressly authorized to provide the notice. *Compare id.* § 262(*l*)(8)(A) (emphasis added), *with id.* § 262(m)(3).

Amgen's interpretation, under which notice may not come until after FDA licensure, would transform this mere "[n]otice" provision into the functional equivalent of an automatic, bondless six-month injunction – even when the sponsor has no valid patents. And, as the district court explained, for each first-approved biosimilar, Amgen's reading would "tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A)." A13. "Had Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so." A13-14.

3. Amgen's recourse is limited to what the BPCIA itself provides

Even if Amgen's interpretation of the BPCIA were correct, the district court correctly concluded that courts may not fashion additional remedies Congress did not provide or "hunt . . . through the laws of the fifty states to find a predicate by which to litigate a claimed BPCIA violation." A8 n.4.

Contrary to Amgen's assertion that the BPCIA does not explicitly make the remedies provided therein "exclusive" (Mot. 15), the BPCIA does exactly that for an applicant's non-disclosure of its application. The BPCIA's amendment to the Patent Act provides that "if the applicant . . . fails to provide the application" to the sponsor, the submission of the application to FDA constitutes an artificial act of infringement. 35 U.S.C. § 271(e)(2)(C)(ii). The statute then specifies patent-

specific remedies that a sponsor may seek in response. *Id.* § 271(e)(4)(A)-(D). Critically, the statute expressly provides that those remedies "are the *only remedies* which may be granted" for the statute's acts of artificial infringement. *Id.* § 271(e)(4) (emphasis added). And those remedies require proof that the proposed biologic will infringe a valid patent claim. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354-56 (Fed. Cir. 2003). Although Amgen cites the exclusive-remedies provision in Section 271(e)(4) as an example of how Congress goes about expressly foreclosing additional relief when it so chooses (Mot. 15), Amgen fails to recognize that the provision expressly prescribes the exclusive remedies for the very conduct of which Amgen complains – submitting a biologics application to the FDA while "fail[ing] to provide the application and information required under section [262](*l*)(2)(A)." 35 U.S.C. § 271(e)(2)(C)(ii), (4).

The BPCIA likewise expressly provides the remedy for an applicant's failure to comply with the notice of commercial marketing provision, namely, immediate patent litigation by the sponsor. 42 U.S.C. § 262(*l*)(9)(B) (cross-referencing, *inter alia*, *id.* § 262(*l*)(8)(A)).

Unsatisfied with the BPCIA's patent remedies, Amgen suggests the creation of an implied federal right of action for an injunction to enforce the BPCIA's procedural steps. Mot. 14. But Amgen's complaint asserted no such claim, instead asserting *only* California law claims (and a patent claim). A73-80. The district

court thus correctly held waived any such claim. A8 n.4.

In any event, Amgen makes no attempt to address the governing standard for creating an implied right of action. *See, e.g.*, *Alexander v. Sandoval*, 532 U.S. 275 (2001). Nor does it cite any evidence of affirmative congressional intent to create the remedy it seeks, as it is required to do. *Id.* at 286-87. Moreover, the BPCIA's creation of its own remedies – regardless of whether they are to Amgen's liking – defeats the effort to imply additional ones. *Id.* at 290.

Amgen's effort to use state law to enforce the BPCIA also fails, for multiple reasons. First, Sandoz did nothing "unlawful." A14-15. Second, California law provides that UCL remedies are not permitted where, as here, the underlying law "expressly provide[s]" that its remedies are exclusive. Cal. Bus. & Prof. Code § 17205; *see* 35 U.S.C. § 271(e)(4) (exclusive remedies provision). Third, the balancing of the equities required under the UCL, *Cortez v. Purolator Air Filtration Prods. Co.*, 999 P.2d 706, 717 (Cal. 2000), leads to the same conclusion because Congress itself already has balanced those equities and provided tailored remedies. Finally, Amgen cannot show conversion of an intangible property right because, *inter alia*, the BPCIA permits applicants to use Amgen's application to file their own applications. 42 U.S.C. § 262(k)(2)(A)(iii).

B. Amgen Has Not Shown A Likelihood Of Irreparable Harm

Amgen's motion should be denied for the independent reason that, as the

district court found, Amgen cannot establish irreparable harm. A2080. That finding is not clearly erroneous. *See Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1010-11 (Fed. Cir. 2009) (irreparable harm reviewed for clear error).

No infringement of a valid patent. As the district court concluded, Amgen's purported harms "are based on the as-yet unproven premise that Sandoz has infringed a valid patent belonging to Amgen." A18. "[A]ny detriment Amgen endures due to market entry of Sandoz's biosimilar product is only undue if Sandoz has infringed an Amgen patent." A2080.

Amgen asserts it is harmed not from infringement but from Sandoz's failure to "compl[y]" with the BPCIA. Mot. 16. But even if Sandoz had followed the procedures Amgen seeks to enforce, those procedures ultimately would have led at most to Amgen's being able to file a suit for patent infringement. 42 U.S.C. § 262(*l*)(6), (8)(B). Showing infringement is the *only* way the BPCIA contemplates a sponsor's keeping a biosimilar off the market. Although Amgen asserted a patent claim in its complaint (and has now had Sandoz's application for more than two months), it has not pressed for adjudication of *any* of its patent rights. As the district court found, "[i]t must, therefore, be assumed" for purposes of this case "that no such infringement has occurred." A18.

Contrary to Amgen's suggestion (Mot. 16), Sandoz's withholding of its application did not "materially prejudice[] Amgen" but in fact *enhanced* Amgen's

ability to protect any patent rights. Had the patent-exchange steps been completed, Sandoz would have had control over how many and which patents would be litigated. 42 U.S.C. § 262(*l*)(4)(B), (5). Sandoz's withholding of its application allowed Amgen to sue for patent infringement much earlier on the patents of Amgen's choosing. *Id.* § 262(*l*)(9)(C).

Nor did Sandoz's July 2014 notice of commercial marketing "den[y] Amgen the statutory period to seek a preliminary injunction." Mot. 16. Nothing prevented Amgen from seeking a preliminary injunction during the 180 days after that notice.

No price erosion. The finding that Amgen's price-erosion claim is speculative is not clearly erroneous. A2080. [redacted] Amgen's declaration and expert report state at most that Amgen "might" or "may" lower its prices upon Sandoz's entry. A479; A516. Amgen's expert admitted that any price erosion was "highly uncertain." A895-96. Sandoz's expert concluded the price-erosion claim was unfounded. A1045-48. And any price erosion could be remedied by patent-infringement damages. *Altana Pharma*, 566 F.3d at 1010-11.

No harm to goodwill. Amgen's theory of harm to goodwill is equally

unavailing. Amgen argues that *if* Sandoz's launch forces Amgen to lower prices, *if* Amgen thereafter forces removal of Sandoz's product from the market, *and if* Amgen then tries to rapidly rehabilitate Neupogen® prices, Amgen's customer relations will be harmed. But as explained above, the record does not support a significant price reduction by Amgen. Nor has Amgen tried to establish it will be able to enforce any patent rights to remove Sandoz's product from the market.

No "patent uncertainty." Amgen fashions a novel theory of harm that it calls "patent uncertainty." Amgen cites no authority suggesting that any court has ever held that this is a legally cognizable harm, let alone an irreparable one.

Amgen argues its 400-patent portfolio is somehow diminished because, without Sandoz's application, it was "impossible for Amgen to determine which of [its] patents read on the manufacture of Sandoz's biological product." Mot. 18. But this very suit belies Amgen's argument: Amgen was able to file the patent suit Congress contemplated, and having filed it, contends it has learned through discovery about additional patent claims it could assert. Sandoz's withholding its application put Amgen in a *better* position to enforce its patent rights, permitting it to sue much earlier. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). But Amgen has now had Sandoz's application for more than two months, and yet it did not add any patent claims to the one it asserted in its original complaint.

Amgen's actions inconsistent with claimed harms. Although Amgen

argues it was harmed by not having Sandoz's application, Amgen rejected Sandoz's repeated offers to provide it. A1481-82; A1505-07. Any harm is "self-inflicted, [and] does not qualify as irreparable." *Caplan v. Fellheimer Eichen Braverman & Kaskey*, 68 F.3d 828, 839 (3d Cir. 1995). Moreover, Amgen's delays in suing and seeking a preliminary injunction negate its claimed irreparable harm. *Apple Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012).

Any harm outside California not relevant. The broadest injunction Amgen could obtain in this state-law suit would apply only to "conduct occurring within California." *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1360 (Fed. Cir. 2013) (reversing nationwide injunction), *pet. for cert. filed*, 82 U.S.L.W. 3690 (U.S. May 15, 2014). Amgen thus must show it would be irreparably harmed if Sandoz's launch *extends to California*, as compared to being limited to the rest of the United States. Amgen has not tried to make any California-specific showing.

C. The Balance Of Hardships Weighs In Sandoz's Favor

Through considerable investment, Sandoz currently enjoys a significant head start over two biosimilar filgrastim applicants expected to receive approval and launch in 2015 or early 2016. A1063. Even an injunction pending an expedited appeal thus could cause Sandoz substantial harm. A1060-68. By contrast, Amgen already has enjoyed double the 12-year exclusivity period Congress decided sufficient to reward biologics innovation. 42 U.S.C. § 262(k)(7)(A).

D. An Injunction Would Disserve The Public Interest

The public interest disfavors an injunction. The consumer interest in more affordable filgrastim would be harmed by an injunction.

II. ANY INJUNCTION MUST BE LIMITED IN SCOPE AND CONDITIONED ON THE POSTING OF A SIGNIFICANT BOND

No injunction pending appeal is warranted. But were an injunction to be issued, it must be limited to conduct in California. *Allergan*, 738 F.3d at 1358-60. Moreover, the only act for which Amgen alleges any potential harm is launching. *See, e.g.*, Mot. 16-19. Any injunction pending appeal should thus prohibit Sandoz only from launching its filgrastim product – i.e., shipping its product to customers in commercial quantities – in California, and nothing more.

Finally, Amgen agrees it must post a bond if an injunction issues. Mot. 19. Because the bond is typically a ceiling on damages from being wrongfully enjoined, courts "should err on the high side." *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000). Any injunction should be conditioned on a bond protecting Sandoz for the maximum duration an injunction could last – 410 days under Amgen's BPCIA interpretation. The harm to Sandoz from an erroneous nationwide injunction of 410 days would exceed [redacted] A1060-68. To ensure a sufficient bond, any bond should be 120% of that: [redacted]

CONCLUSION

Amgen's motion for an injunction pending appeal should be denied.

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Respectfully submitted,

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